K012167

AUG - 1 2001

510(k) SUMMARY

Invacare Corporation's
Model Top End Terminator Titanium Manual Wheelchair

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Rae Ann Farrow
Manager, Regulatory Compliance

Date Prepared: June 26, 2001

Name of Device and Name/Address of Sponsor

Model Top End Terminator Titanium Manual Wheelchair
Invacare Corporation
One Invacare Way
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical 89IOR

Predicate Devices
The Invacare Top End Terminator Titanium is substantially equivalent to the Model "Top End Terminator" Manual Wheelchair **(K922535 7/24/92)** and the "Top End Terminator SS Manual Wheelchair" **(K990157, 3/4/99)**.

Intended Use: The intended use of the Model Top End Terminator Titanium Manual Wheelchair is to provide mobility to persons limited to a sitting position.

Technological Characteristics and Substantial Equivalence

Device Description The Invacare Corporation Model Top End Terminator Titanium is a manually operated, self-propelled, manual, mechanical wheelchair. Its intended function and use is to provide mobility to persons who may be restricted to a sitting position.

The product consists of a titanium frame, large rear wheels with handrims for propelling the chair, and smaller front pivoting casters for steering and turning. The product is designed to be a lightweight, user adaptable, everyday wheelchair, for both indoor and outdoor use. It is a rigid or non-folding type wheelchair, which has a more sporty appearance than the traditional type of manual wheelchairs.

The Top End Terminator Titanium Wheelchair incorporates a one-piece frame. The frame is constructed from 1" diameter, 3-2.5 seamless titanium tubing that is brazed together. The wheelchair adjustable tension back upholstery consists of U850 ballistic material with fiber batting and the wheelchair adjustable tension seat upholstery consists of U240 nylon and webbing. Both upholstery types meet a minimum of the California Bureau of Home Furnishings 116 and 117 Flammability Standards.

Substantial Equivalence The Invacare Top End Terminator Titanium is substantially equivalent to the Model "Top End Terminator" Manual Wheelchair **(K922535 7/24/92)** and the "Top End Terminator SS Manual Wheelchair" **(K990157, 3/4/99)**.

Performance Data

The Invacare Top End Terminator SS Manual Wheelchair meets the applicable performance requirements specified in:

- Rehabilitation Engineering Society of North America (RESNA) Standard ANSI/RESNA WC/Vol.1-1998 "Requirements and Test Methods for Wheelchairs (Including Scooters).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2001

Ms. Rae Ann Farrow
Manager, Regulatory Compliance
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036

Re: K012167
Trade/Device Name: Top End Terminator Titanium Manual
Regulation Number: 890.3850
Regulatory Class: I
Product Code: IOR
Dated: July 10, 2001
Received: July 12, 2001

Dear Ms. Farrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): *TBD* K012167

Device Name: *Top End Terminator Titanium Manual Wheelchair*

Indications For Use:

The intended use of the Model Top End Terminator Titanium Manual Wheelchair is to provide mobility to persons limited to a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K012167

Prescription Use ____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109)

510(k) Number